UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,974	06/29/2006	Benny Pesach	227/04957	6427

44909 7590 01/31/2011

PRTSI
P.O. Box 16446
Arlington, VA 22215

EXAMINER	
LIU, CHU CHUAN	
ART UNIT	PAPER NUMBER
3777	
MAIL DATE	DELIVERY MODE
01/31/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/559,974	PESACH ET AL.	
	Examiner	Art Unit	
	CHU CHUAN LIU	3777	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 June 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *01/31/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claims 12, 15, 25, 29, 32, 40, 42, 45 and 47 are objected to because of the following informalities: In regard to claims 12, 25, 29, 32, 40, 42, 45 and 47, the word “and” before “comprising” should be deleted. In regard to claim 15, the term “responsive to reflected ultrasound” lacks an antecedent basis. Appropriate corrections are required.

Claim Rejections - 35 USC § 101

2. Claims 17 and 19 are rejected under 35 U.S.C. 101 because claims 17 and 19 improperly define the apparatus in relation to the human body. In regard to claims 17 and 19, the phrase of “presses against the skin” should be replaced by a suggested phrase of either “is adapted to press” or “presses against the skin when the mounting module is adhered to the skin" which would avoid positively claiming the relation.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-6, 12, 17-20, 27-35, 37-41 and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,348,002 to Caro (Caro). In regard to claim 1, Caro discloses an apparatus (control unit 111 in Fig. 2 and the apparatus of Fig. 15. The element numbers of the apparatus illustrated in Fig. 15 are referring to Fig. 11. See Col 22 lines 36-52) for assaying an analyte of blood in a patient's blood vessel (Col 6

lines 5-30, Col 22 lines 40-52, and Col 23 lines 6-12) comprising: a mounting module (element 101, Fig. 11) adapted so that it can be adhered to the skin of the patient (skin 223, Fig. 15) overlying a tissue region comprising the blood vessel (subdermal tissue 221, Fig. 15); a sensor unit mounted to the module (elements 108 and 117, Fig. 11) that generates signals responsive to characteristics of the tissue region (Col 6 lines 18-30); and a controller (control unit 111, Fig. 2) that receives the signals and uses received signals (Fig. 8) to assay the analyte (Col 23 lines 6-12) and to determine a degree to which the sensor unit is aligned with the blood vessel (the magnitude of the amplitude of the detected acoustic signal is related to the level of blood contained in the tissue region, Fig. 8. In the configuration of Fig. 15, the sensor could scan multiple areas on the skin. Therefore, the controller is cable of obtaining the information of the alignment between the sensor and the blood vessel).

In regard to claim 2, Caro discloses the sensor unit comprises at least one light source that illuminates the region with light (light source 124, Fig. 2) at at least one wavelength that is absorbed and/or scattered by the analyte (Fig. 8; claims 8 and 9; the wavelength range of 400nm to 3000nm, Col 10 lines 6-10) and generates photoacoustic waves in the region (Col 6 lines 18-30) and at least one acoustic transducer that generates at least some of the signals responsive to the photoacoustic waves (transducer 108, Fig. 11).

In regard to claim 3, Caro discloses the controller uses signals responsive to the photoacoustic waves to assay the analyte (Fig. 8).

In regard to claim 4, Caro discloses the light source illuminates the region with light (the wavelength range of 400nm to 3000nm, Col 10 lines 6-10) that is absorbed by red blood cells (It is well known that red blood cell would absorb light within the wavelength range).

In regard to claim 5, Caro discloses the controller uses at least one characteristic of the photoacoustic signals (Col 13 line 37- Col 14 line 4; Figs. 5 and 6) to determine a degree to which the sensor unit is aligned with the blood vessel (according to the embodiment illustrated in Fig. 15, the device can obtain different measurements in multiple scanning areas on the skin 224. The magnitude of the amplitude of the detected acoustic signal is related to the level of blood contained in the tissue region, Fig. 8. Therefore, the level of blood contained in a particular tissue region can be determined).

In regard to claim 6, Caro discloses the at least one characteristic comprises a magnitude of the amplitude of the signal (Col 7 lines 49-61).

In regard to claim 12, Caro discloses the apparatus comprises a display screen (Fig. 8).

In regard to claim 17, Caro discloses at least a portion of the sensor unit presses against the skin to provide optical and/or acoustic coupling of the sensor to the skin (Fig. 15).

In regard to claim 18, Caro discloses the controller uses signals received from the sensor unit to determine if the sensor portion exerts excessive pressure on the

blood vessel (the magnitude of the amplitude of the detected acoustic signal is related to the level of blood contained in the tissue region, Fig. 8).

In regard to claim 19, Caro discloses an apparatus (control unit 111 in Fig. 2 and the apparatus of Fig. 15. The element numbers of the apparatus illustrated in Fig. 15 are referring to Fig. 11. See Col 22 lines 36-52) for assaying an analyte of blood in a patient's blood vessel (Col 6 lines 5-30, Col 22 lines 40-52, and Col 23 lines 6-12) comprising: a mounting module (element 101, Fig. 11) adapted so that it can be adhered to the skin of the patient (skin 223, Fig. 15) overlying a tissue region comprising the blood vessel (subdermal tissue 221, Fig. 15); a sensor unit mounted to the module (elements 108 and 117, Fig. 11) that generates signals responsive to characteristics of the tissue region (Col 6 lines 18-30) wherein at least a portion of the sensor unit presses against the skin to provide optical and/or acoustic coupling of the sensor to the skin (Fig. 15); a controller (control unit 111, Fig. 2) that receives the signals and uses received signals (Fig. 8) to assay the analyte (Col 23 lines 6-12) and to determine if the sensor portion exerts excessive pressure on the blood vessel (the magnitude of the amplitude of the detected acoustic signal can indicate the amount of blood in the irradiated tissue region, Fig. 8. When the sensor portion exerts excessive pressure on the blood vessel, minimum amount of blood would be contained in the irradiated tissue region).

In regard to claim 20, Caro discloses the sensor unit comprises at least one light source that illuminates the region with light (light source 124, Fig. 2) at at least one (the wavelength range of 400nm to 3000nm, Col 10 lines 6-10) that generates photoacoustic

waves in the region (Col 6 lines 18-30) and at least one acoustic transducer that generates at least some of the signals responsive to the photoacoustic waves (transducer 108, Fig. 11).

In regard to claim 27, Caro discloses the mounting module comprises a frame having sides (beam expansion means 117, Fig. 11), which at least partially surround a region (region on the skin 223, Fig. 15) that receives the sensor unit.

In regard to claim 28, Caro discloses the region that receives the sensor unit is an open region (beam expansion means 117, Fig. 11) and when the sensor unit is positioned in the region no portion of the mounting module intervenes between the sensor unit and the skin (Fig. 15).

In regard to claim 29, Caro discloses an adhesive (Col 9 lines 7-11) that attaches the sensor unit to the skin when the sensor unit is mounted in the open receiving region (The transducer 108 is adjacent to the beam expansion means 117. According to the embodiment illustrated in Fig. 15, the liquid or gel applied on the transducer will also cover the surface of means 117).

In regard to claim 30, Caro discloses the adhesive (Col 9 lines 7-11. The transducer 108 is adjacent to the beam expansion means 117. According to the embodiment illustrated in Fig. 15, the liquid or gel applied on the transducer will also cover the surface of means 117) is substantially transparent to light provided by the at least one light source (It is known that most conventional adhesive of the liquid, such as water, or gel for ultrasound transducers is substantially transparent to light).

In regard to claim 31, Caro discloses the adhesive is a relatively good conductor of sound and reduces acoustic impedance mismatch between the sensor unit and the skin (Col 9 lines 7-14).

In regard to claim 32, Caro discloses the apparatus comprises a gel (Col 9 lines 7-14) that optically and acoustically couples the sensor unit to the skin when the sensor unit is mounted in the open receiving region (Fig. 15).

In regard to claim 33, Caro discloses the frame (element 101, Fig. 11) comprises a panel (silica surface 213 is disposed on beam expansion means 117 in one embodiment of Fig. 14, Col 21 lines 62-66) that connects the sides (surroundings of beam expansion means 117 and transducer 108, Figs. 11 and 15) and which intervenes between the sensor unit and the skin when the sensor unit is mounted in the receiving region (Fig. 15).

In regard to claim 34, Caro discloses the panel is flexible (silica surface 213, Fig. 14; Col 21 lines 62-66. A thin layer of silica surface could be flexible).

In regard to claim 35, Caro discloses the panel is substantially transparent to light provided by the at least one light source (silica surface 213, Fig. 14 and Col 21 lines 62-66).

In regard to claim 37, Caro discloses the panel comprises an adhesive layer (Col 9 lines 7-11 and Col 20 lines 16-25. The transducer 108 is adjacent to the beam expansion means 117. According to the embodiment illustrated in Fig. 15, the liquid or gel applied on the transducer will also cover the surface of means while scanning multiple areas) that bonds the panel and thereby the mounting module to the skin.

In regard to claim 38, Caro discloses the adhesive is substantially transparent to light provided by the at least one light source (It is known that most conventional adhesive of the liquid, such as water, or gel for ultrasound transducers is substantially transparent to light).

In regard to claim 39, Caro discloses the adhesive is a relatively good conductor of sound and reduces acoustic impedance mismatch between the panel and the skin (Col 9 lines 7-14).

In regard to claim 40, Caro discloses a gel (gel, Col 9 lines 7-14 and Col 23 lines 7-16) that optically and acoustically couples the sensor unit to the panel when the sensor unit is mounted in the receiving region.

In regard to claim 41, Caro discloses the frame comprises at least one elastic element (element 101, Fig. 15. The member of the element 101 can be plastic, resilient foams, rubber disks or bands, Col 8 lines 43-51) that exerts a resilient force on the sensor unit substantially parallel to the plane of the frame to maintain the sensor unit securely in position in the frame (Fig. 11).

In regard to claim 48, Caro discloses the analyte is glucose (Col 23 lines 6-12).

4. Claims 1, 17-18, 23-26 and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,769,076 to Maekawa *et al.* (Maekawa). In regard to claim 1, Maekawa discloses an apparatus for assaying an analyte of blood in a patient's blood vessel (Fig. 6 and claim 1) comprising: a mounting module (probe 58, Fig. 6) adapted so that it can be adhered to the skin of the patient overlying a tissue region

comprising the blood vessel (Fig. 6 and Claim 1); a sensor unit (CCD 40a, Fig. 6) mounted to the module that generates signals responsive to characteristics of the tissue region (Col 6 lines 28-34); and a controller (controller 98, Fig. 6) that receives the signals and uses received signals to assay the analyte (hemoglobin, Col 6 lines 30-34) and to determine a degree to which the sensor unit is aligned with the blood vessel (Col 4 lines 40-44).

In regard to claim 17, Maekawa discloses at least a portion of the sensor unit presses against the skin (tip 59 of probe 58, Fig. 6) to provide optical coupling of the sensor to the skin (transparent plate 66, Fig. 6).

In regard to claim 18, Maekawa discloses the controller uses signals received from the sensor unit to determine if the sensor portion exerts excessive pressure on the blood vessel (Col 6 lines 50-60).

In regard to claim 23, Maekawa discloses the sensor portion position is movable relative to the mounting module in a direction substantially perpendicular to the skin (manipulator 89, Fig. 10 and Col 7 lines 41-62) so as to adjust pressure that the sensor unit portion exerts on the skin and thereby on the blood vessel (position control portion 92, Fig. 10 and Col 7 lines 41-55).

In regard to claim 24, Maekawa discloses the position of the sensor portion is manually adjustable (Fig. 11 and Col 7 lines 41-55).

In regard to claim 25, Maekawa discloses a motor (motor micrometer head 83, Fig. 6) controllable to adjust the position of the sensor unit portion (Fig. 6).

In regard to claim 26, Maekawa discloses the controller controls the motor to adjust position of the sensor unit portion (Col 8 lines 20-29) if the controller determines that the sensor unit portion exerts excessive pressure on the skin (image contrast, Col 6 lines 50-54 and the diameter D of blood vessel, Col 8 lines 8-19).

In regard to claim 47, Maekawa discloses a motor (motor micrometer head 83, Fig. 6) controllable to adjust the position of the sensor unit relative to the mounting module in a direction parallel to the skin (Figs. 6 and 7) and wherein the controller controls the motor to adjust position of the sensor unit if signals received from the sensor unit indicate alignment of the sensor unit is unsatisfactory (Col 8 lines 8-29).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 7-8 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,348,002 to Caro (Caro) as applied to claim 1 above, and further in view of U.S. Patent No. 5,840,023 to Oraevsky *et al.* (Oraevsky). In regard to claim 7, Caro discloses all the claim limitations except the at least one characteristic comprises shape of the signal. Oraevsky teaches an optoacoustic imaging device (Fig. 4) to detect photoacoustic signals (signal 16, Fig. 5) from the tissue region containing blood vessel

(Fig. 4) and the shape of the detected photoacoustic signals indicates the depths of the blood vessel (small blood vessels (1 and 2) and large blood vessels (3, 4 and 5), Fig. 5; Col 6 line 66 – Col 7 line 12). It is known that the shape of a detected photoacoustic signal could indicate the relationship between the size and the location of a blood vessel. Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention was made to modify the characteristic of the photoacoustic signals (Caro) to incorporate the shape of the signal (Oraevsky) in order to obtain more accurate alignment between the sensor and the blood vessel.

In regard to claim 8, Caro as modified by Oraevsky discloses the at least one characteristic comprises a time dependence of the signal (Fig. 5 of Oraevsky).

In regard to claim 13, Caro as modified by Oraevsky discloses the controller displays data that relates to a degree to which the sensor unit is aligned with the blood vessel on the display screen (Fig. 5 of Oraevsky).

7. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,348,002 to Caro (Caro) as applied to claim 1 above, and further in view of U.S. Patent No.5,598,841 to Taniji *et al.* (Taniji). Caro discloses all the claim limitations except at least one characteristic comprises a power spectrum of the signal. Taniji teaches a characteristic comprises a power spectrum of the signal (Figs 1 and 2). Taniji determines the blood flow by utilizing a laser beam to irradiate a blood vessel and detect the reflected signal for the power spectrum function analysis. It is known that the reflected energy from the irradiated region contains information of the amount of blood

flowing in the target area. Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention was made to modify the characteristic (Caro) to incorporate the power spectrum analysis (Taniji) of the detected signal in order to process the data and obtain more accurate determinations of the alignment of the sensor and the blood vessel.

8. Claim 10-11, 14-15 and 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,348,002 to Caro (Caro) as applied to claims 1 and 19 above, and further in view of U.S. Patent No. 4,567,898 to Plugge *et al.* (Plugge). In regard to claim 10, Caro discloses the controller controls the at least one transducer (transducer 108, Fig. 11) generates at least some of the signals responsive to ultrasound reflected from features comprised in the region (Col 6 lines 18-30)). Caro does not specifically discloses the controller controls the at least one transducer to transmit ultrasound into the region. Plugge teaches the controller controls the at least one transducer to transmit ultrasound into the region (Col 1 line 64 - Col 2 line 6). It is well known that a conventional ultrasound transducer can be utilized to emit and detect acoustic waves and generate ultrasound images. Caro discloses the transducer 108 may be any conventional type and construction such PZT, PVDF or PVDF2, Col 9 lines 15-26. Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention was made to modify the transducer (Caro) to transmit ultrasound into the region in order to facilitate the detection of blood vessel.

In regard to claim 11, Caro discloses the controller uses signals generated responsive to reflected photoacoustic signal (Fig. 8) to determine a degree to which the sensor is aligned with the blood vessel (the oxygen concentration is related to the level of blood contained in the tissue region, Fig. 8 and claim 9). Caro does not specifically disclose the controller uses signals generated responsive to reflected ultrasound. Plugge teaches the controller uses signals generated responsive to reflected ultrasound (Col 1 line 64 - Col 2 line 6) to determine a degree to which the sensor is aligned with the blood vessel (ultrasound image of blood vessel, Figs. 2A and 2B). Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention was made to modify the transducer (Caro) to detected the reflected ultrasound (Plugge) in order to obtain more precise measurement of the alignment of the sensor and the blood vessel.

In regard to claim 14, Caro discloses the controller uses signals from the at least one acoustic transducer (Fig. 8). Caro does not specifically disclose to generate an image of the blood vessel and displays the image on the screen. Plugge teaches the controller uses signals from an acoustic transducer to generate an image of the blood vessel (Figs. 1 and 2) and displays the image on the screen (display, Fig. 1). Plugge further teaches an image of the blood vessel can be obtained by a conventional B-scanner (Col 2 lines 1-6). It would have been obvious to one with ordinary skill in the art at the time of the invention was made to modify the controller (Caro) to incorporate an conventional ultrasound B-scanner (Plugge) in order to generate an image of blood

vessel in the region of interest of the tissue for align the sensor and blood vessel more efficiently.

In regard to claim 15, claim 15 encompasses the same scope of the invention as that of the claim 14. Therefore, claim 15 is rejected on the same ground as the claim 14.

In regard to claim 21, claim 21 encompasses the same scope of the invention as that of the claim 10. Therefore, claim 21 is rejected on the same ground as the claim 10.

In regard to claim 22, Caro discloses all the claim limitations except the controller uses the signals to generate an image of the blood vessel and if the image indicates that the blood vessel is deformed relative to a normative blood vessel shape, the controller determines that the sensor portion exerts excessive pressure. Plugge teaches the controller uses signals to generate an image of the blood vessel (Figs. 2A and 2B) and if the image indicates that the blood vessel is deformed relative to a normative blood vessel shape, the controller determines that the sensor portion exerts excessive pressure (the information of the shape of the imaged blood vessel can facilitate the determination if the sensor portion exerts excessive pressure, Figs. 2A and 2B). It would have been obvious to one with ordinary skill in the art at the time of the invention was made to modify the controller (Caro) to incorporate an conventional ultrasound B-scanner (Plugge) for generating an image of the blood vessel in order to determine if the sensor portion exerts excessive pressure to the tissue more efficiently.

7. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,348,002 to Caro (Caro) as applied to claim 1 above, further in view of U.S.

Patent No. 4,567,898 to Plugge *et al.* (Plugge) as applied to claims 10-11 and 14-15 above, and further in view of U.S. Patent No. 6,196,226 to Hochman *et al.* (Hochman). In regard to claim 16, Caro as modified by Plugge discloses all the claim limitations except the controller displays a fiducial on the screen and wherein a distance on the screen between the fiducial and the image of the blood vessel indicates a degree to which the sensor unit is misaligned with the blood vessel. Hochman teaches the controller displays a fiducial on the screen and wherein a distance on the screen between the fiducial and the image indicates a degree to which the sensor unit is misaligned with the corresponding area (Col 6 lines 8-20 and asterisks in Fig. 6). Caro as modified by Plugge discloses the apparatus has the ability to generate images while performing measurements at a region of tissue. Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention was made to modify the controller (Caro as modified by Plugge) to display a fiducial (Hochman) in order to obtain more accurate measurement of the alignment between the sensor and the blood vessel.

8. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,348,002 to Caro (Caro) as applied to claim 1 above, further in view of U.S. Patent No. 5,469,852 to Nakamura *et al.* (Nakamura). In regard to claim 36, Caro discloses all the claim limitation except the panel is a relatively good conductor of sound. Nakamura teaches a panel (acoustic window 44, Fig. 3A) is a relatively good conductor of sound (filled with acoustic liquid 42 and made of transparent plastics, Col 6

lines 17-28). According to Fig. 15 of Caro, the transducer 108 and the beam expanding means 117 are adapted to contact a surface of skin. It would have been obvious to one with ordinary skill in the art at the time of the invention was made to modify the sensor (Caro) to incorporate a panel (Nakamura) in order to protect the photoacoustic sensor from possible contaminations during the measurement.

9. Claims 42-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,348,002 to Caro (Caro) as applied to claim 1 above, further in view of U.S. Patent No. 5,769,076 to Maekawa. In regard to claim 42, Caro discloses all the claim limitations except the apparatus comprises at least one set screw having a position that limits motion of the sensor unit in a direction that the resilient force operates to move the sensor unit. Caro further discloses the apparatus (Figs. 2 and 11) can be configured to measure blood oxygenation from the external skin of the tissue (Fig. 15 and Col 22 lines 36-62). Maekawa teaches an apparatus (Figs. 6 and 7) comprises at least one set screw (tip of rod 84, Fig. 7. It is well known that a screw type mechanism is required in order to transfer the rotation movements into longitudinally movements. If not inherent, screw type mechanism motor drives are well known as shown by Griffith *et al.*, U.S. Patent No. 6,088,605) having a position that limits motion of the sensor unit (tip 59 of the probe 58 and sliding board 59b, Figs. 6 and 7) in a direction (direction a or b, Figs.6 and 7) that the resilient force (coiled springs 85a and 85b; leaf springs 82, Fig. 7) operates to move the sensor unit. It is well known at the time the invention was made (as evidenced by U.S. Patent No. 5,456,256, and U.S.

Patent No. 6,088,605) that a motor-driven scanning mechanism can provide precise movements of the sensor. Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention was made to modify the apparatus (Caro) to incorporate a motor-driven scanning mechanism (Maekawa) in order to obtain more precise measurements of the alignment between the blood vessel and the sensor unit.

In regard to claim 43, Caro as modified by Maekawa discloses the set screw (tip of rod 84, Fig. 7 of Maekawa) is mounted in the frame (L-shaped bracket 71, Figs. 6 and 7).

In regard to claim 44, Caro as modified by Maekawa discloses the set screw is adjustable manually (rotate the rod 84 to push the sliding board 59b, Fig. 7).

In regard to claim 45, Caro as modified by Maekawa discloses the apparatus comprises a motor (motor micrometer head 83, Figs. 6 and 7 of Maekawa) controllable to adjust the position of the set-screw.

In regard to claim 46, Caro as modified by Maekawa discloses the controller controls the motor to adjust position of the sensor unit if signals received from the sensor unit indicate alignment of the sensor unit is unsatisfactory (Col 8 lines 8-32 of Maekawa).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Griffith *et al.* (U.S. Patent No. 6,088,605) teaches an apparatus for noninvasive blood glucose sensing (stepper motor 20, solenoid 60, movable sensor

head 8, and reciprocating lead screw 22, Figs. 2-4). Archibald *et al.* (U.S. Patent. No. 5,450,852) teaches a noninvasive blood pressure monitoring system with a motor controllable mechanism for applying pressure to the sensor unit (Figs. 3 and 4). Kruger (U.S. Patent No. 5,713,356) teaches a photoacoustic breast scanner utilizing laser-generated radiation in the ultraviolet, visible, near-infrared band or microwave as the irradiating source and a transducer array to detect the photoacoustic signals/ images (Figs. 5-7 and 13).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHU CHUAN LIU whose telephone number is (571)270-5507. The examiner can normally be reached on M-TH 8:00am~5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tse Chen can be reached on 571-272-3672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Chu Chuan Liu/
Examiner, Art Unit 3777

/Eric F Winakur/
Primary Examiner, Art Unit 3777